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**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
OFFICE OF ADMINISTRATIVE LAW JUDGES**

**In the Matter of**

**Edwards Lifesciences Corp.**

**and**

**JenaValve Technology, Inc.**

**Docket No. 9442**

**Public Version**

**RESPONDENT JENAVALVE TECHNOLOGY, INC.'S  
ANSWER AND DEFENSES**

Pursuant to Rule 3.12, Respondent JenaValve Technology, Inc. (“JenaValve”) hereby answers the Commission’s Complaint (“Complaint”).

All allegations not expressly admitted herein are denied. To the extent the Complaint defines TAVR-AR to include only those devices being developed by Defendants, that definition is expressly denied. JenaValve does not interpret headings or subheadings in the Complaint as well-pleaded allegations to which any response is required. To the extent such a response is required, they are denied. JenaValve reserves the right to amend and/or supplement this Answer and Defenses.<sup>1</sup>

**Response to the Complaint’s Specific Allegations**

Each paragraph below corresponds to the same-numbered paragraph in the Complaint:

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<sup>1</sup> For clarity, references to sentence numbering refer to quotes as single sentences even if the quote has multiple sentences within that quote.

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1. JenaValve admits the first sentence. As to the remaining sentences, to the extent they pertain to JenaValve, JenaValve denies the allegations. JenaValve admits that it plans to seek FDA approval for Trilogy in the future, but otherwise denies any characterization of its expectations. To the extent the allegations pertain to Edwards or other parties, JenaValve lacks knowledge or information sufficient to form a belief and therefore denies those allegations.

2. JenaValve admits that Edwards executed an agreement to acquire JenaValve. JenaValve denies that it was “thunderstruck” by Edwards’ acquisition of JC Medical. To the extent the paragraph quotes or characterizes Edwards or JenaValve documents, JenaValve respectfully refers the Court to those documents and denies any mischaracterization. JenaValve otherwise denies the remaining allegations.

3. JenaValve admits that at least 8 million Americans over age 50 suffer from aortic regurgitation (“AR”). JenaValve admits that AR is a serious and often fatal condition in which the heart’s aortic valve does not close properly, allowing blood to backflow into the heart. JenaValve admits that, over time, this can lead to the left ventricle becoming enlarged and weakened, potentially resulting in heart failure. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations and therefore denies them.

4. JenaValve admits the first and second sentences. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence and therefore denies the allegations. As to the fourth sentence,

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JenaValve admits that TAVR-AR devices, in part, seek to provide a treatment alternative to SAVR for patients for whom invasive surgery is not recommended; JenaValve otherwise denies the allegations. As to the fifth sentence, JenaValve admits that TAVR-AR devices can be significantly less invasive than—and may be an alternative to—SAVR.

5. JenaValve admits that it has completed clinical trials for its TAVR-AR device and submitted its application for Premarket Approval (“PMA”) to the FDA. JenaValve plans to seek FDA approval in the future. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations and therefore denies them.

6. As to the first sentence, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding JC Medical; JenaValve otherwise denies the allegations. As to the second sentence, JenaValve admits it sought to demonstrate Trilogy’s efficacy compared to SAVR; JenaValve otherwise denies the allegations and notes that to the extent the sentence quotes or characterizes documents, and JenaValve respectfully refers the Court to those documents and denies any mischaracterization. JenaValve denies the allegations in sentences three, four, five, and six, and notes that JenaValve has independently pursued improvements and clinical trials, including the ARTIST trial, to expand the addressable patient population. JenaValve’s interest in this patient group predates and is independent of JC Medical’s activities in the United States. To the extent these sentences quote or characterize documents, JenaValve respectfully refers the

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Court to those documents and denies any mischaracterizations. As to the seventh sentence, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

7. Denied.

8. To the extent the allegations pertain to Edwards or other parties, JenaValve lacks knowledge or information sufficient to form a belief about the truth of those allegations and therefore denies them. To the extent the paragraph quotes or characterizes documents, JenaValve respectfully refers the Court to those documents and denies any mischaracterization. JenaValve otherwise denies the remaining allegations.

9. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 and therefore denies the allegations.

10. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 and therefore denies them. To the extent the paragraph quotes or characterizes documents, JenaValve respectfully refers the Court to those documents and denies any mischaracterization.

11. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

12. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

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13. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent a response is required, JenaValve denies the allegations.

14. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent a response is required, JenaValve denies the allegations.

15. JenaValve admits the allegations in the first and second sentences. As to the third, fourth, and fifth sentences, which pertain to Edwards or JC Medical, JenaValve lacks knowledge or information sufficient to form a belief and therefore denies those allegations.

16. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 and therefore denies the allegations.

17. JenaValve admits that it is a medical device company developing TAVR systems for the treatment of aortic valve disease. It admits that it is headquartered in Irvine, California. JenaValve admits that its product, Trilogy, is a TAVR device being developed and designed to treat AR.

18. JenaValve admits to the allegations of the first sentence. As to the second sentence, JenaValve admits that it expects to receive FDA approval for Trilogy in the future, but otherwise denies any characterization of its expectations.

19. JenaValve admits that it executed an Agreement and Plan of Merger with Edwards on or around July 23, 2024, and respectfully refers the Court to that agreement for its full contents. JenaValve otherwise denies the allegations.

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20. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required and to the extent the allegations concern Edwards or JC Medical, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in those sentences and therefore denies them.

21. The first sentence asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies them. To the extent the paragraph purports to quote documents or characterize statements by JenaValve's CEO, JenaValve respectfully refers the Court to those documents and statements and denies any mischaracterization.

22. JenaValve admits and avers that Paragraph 22 purports to provide an incomplete comparison of TAVR and SAVR. JenaValve otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

23. JenaValve admits that TAVR devices for the treatment of aortic stenosis ("AS") are commercially available in the United States, but otherwise lacks knowledge as to when Edwards commercialized its TAVR device to treat AS. JenaValve admits that the paragraph generally describes, albeit in an oversimplified manner, the comparison of AS and AR. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fifth sentence and therefore denies the allegations.

24. As to the first sentence, JenaValve admits that JenaValve's TAVR-AR device is designed specifically to adhere to AR patients' aortic annuli but lacks

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knowledge or information sufficient to form a belief as to the pleaded design intent of JC Medical's TAVR-AR device and therefore denies the allegations. JenaValve admits the allegations in the second sentence. The graphic purports to reflect a document and JenaValve respectfully refers the Court to that document and otherwise denies any mischaracterization of the content.

25. As to the first sentence, JenaValve lacks knowledge or information sufficient to form a belief as to the pleaded design intent of the J-Valve device and therefore denies those allegations; JenaValve otherwise admits the allegations. As to the second sentence, JenaValve denies the allegations.

26. JenaValve admits that TAVR-AR devices are Class III medical devices and must receive PMA approval from the FDA before the device may be sold commercially. Based on its understanding, JenaValve admits that, among other criteria, PMA approval is based on the FDA's determination that the PMA application contains sufficient valid scientific evidence to assure the device is safe and effective for its intended use. As to the fourth sentence, JenaValve admits that it understands that some medical companies conduct early feasibility studies but otherwise denies that this is sufficient to generate sufficient scientific evidence. As to the fifth sentence, JenaValve admits that it understands that some medical companies engage in "pivotal" trials as part of the FDA-approval process, but JenaValve denies that this is a complete description of the FDA-approval process. JenaValve lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in sentences four and five and therefore denies the allegations. As to the sixth sentence,

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JenaValve admits that clinical trials for TAVR-AR devices take time and can be capital intensive, but otherwise lacks sufficient information as to the truth of the allegations to the extent they pertain to parties other than JenaValve, and therefore denies them.

27. JenaValve denies that TAVR-AR devices is a proper relevant antitrust market as defined by the Complaint. Accordingly, JenaValve denies this allegation.

28. As to the first sentence, JenaValve admits that TAVR-AR devices are designed to specifically treat AR; it otherwise denies the allegations. As to the second and third sentences, to the extent the allegations pertain to entities other than JenaValve, JenaValve lacks knowledge or information sufficient to form a belief as to the allegations related to other entities; it otherwise denies the allegations. JenaValve denies the allegations in the fourth sentence.

29. JenaValve denies the allegations in the first, second, and third sentences. As to the fourth sentence, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. As to the fifth sentence, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. The sixth sentence purports to quote from a document, and JenaValve respectfully refers the Court to that document and denies any allegation that mischaracterizes that document. As to the seventh sentence, JenaValve admits that TAVR-AR devices are designed specifically for treating AR. With respect to the eighth sentence, the allegations do not specifically pertain to JenaValve and, therefore,



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JenaValve lacks knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies them.

30. JenaValve denies the allegations in the first sentence. The allegations in the second sentence include other parties to which no answer is required. To the extent an answer is required, JenaValve lacks knowledge or information sufficient to form a belief about the truth of the allegations pertaining to entities other than JenaValve and therefore denies the allegations.

31. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

32. This paragraph asserts legal conclusions and allegations to which no answer is required. JenaValve specifically denies the allegation that purports to suggest that TAVR-AR devices is a relevant product market. JenaValve denies the remaining allegations.

33. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations. Further, Paragraph 33 purports to describe and quote from documents, and JenaValve respectfully refers the Court to those documents and denies any allegation that mischaracterizes those documents.

34. JenaValve lacks knowledge or information sufficient to form a belief about the truth of the allegations pertaining to entities other than JenaValve and

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therefore denies the allegations. To the extent this paragraph pertains to JenaValve, JenaValve denies these allegations.

35. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence, and therefore denies the allegations. As to the second sentence, JenaValve admits that TAVR-AR products require FDA approval to be sold commercially in the United States, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence and therefore denies these allegations.

36. This paragraph asserts legal conclusions and allegations to which no answer is required. JenaValve specifically denies that TAVR-AR devices constitutes a relevant product market. JenaValve denies the remaining allegations.

37. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

38. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies that the proposed acquisition would substantially lessen competition or tend to create a monopoly in any relevant market. JenaValve asserts that the transaction will enhance investments in R&D, accelerate patient access to new therapies, and generate significant patient benefits that cannot be accomplished unilaterally or through alternative transactions. JenaValve denies the remaining allegations in this paragraph.

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39. JenaValve denies the allegations in the first sentence. The second sentence and the purported excerpted document relate to other parties to which no answer is required. To the extent an answer is required, JenaValve lacks knowledge or information sufficient to form a belief about the truth of the allegations pertaining to entities other than JenaValve and therefore denies the allegations.

40. JenaValve denies the allegations in the first sentence. As to the second, third, fourth, fifth, sixth, and seventh sentences, they purport to characterize and quote documents, and JenaValve respectfully refers the Court to those documents and otherwise denies any mischaracterization of their contents. JenaValve denies the allegations in the eighth sentence. JenaValve has long been interested in improving the Trilogy system and expanding the addressable patient population through initiatives such as the ARTIST trial, larger valves, or improved delivery systems. This interest predates and is independent of JC Medical's activities in the United States. JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the ninth sentence and therefore denies the allegations.

41. JenaValve denies the allegations in the first sentence. Sentences two, three, five, six, seven, and eight purport to characterize and quote documents, and JenaValve respectfully refers the Court to those documents and denies any mischaracterization of their contents. JenaValve denies the allegations in sentence four. With respect to sentence nine, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations.

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42. JenaValve denies the allegations in this Paragraph. Further, this paragraph purports to characterize and quote documents, and JenaValve respectfully refers the Court to those documents and denies any mischaracterization of their contents.

43. This paragraph purports to characterize and quote documents, and JenaValve respectfully refers the Court to the full context of those statements and denies any mischaracterization.

44. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

45. JenaValve denies the allegations in this paragraph. Further, this paragraph purports to characterize and quote documents, and JenaValve respectfully refers the Court to those documents and denies any mischaracterization of their contents.

46. JenaValve denies the allegations in the first and fifth sentences. JenaValve admits the allegations in the second sentence. As to the third, fourth, sixth, and seventh sentences, JenaValve lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. Further, the fifth, seventh, and eighth sentences purport to quote from documents and JenaValve respectfully refers the Court to those documents and denies any mischaracterization of their contents.

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47. With respect to the allegations in paragraph 47, JenaValve lacks knowledge or information sufficient to form a belief about the truth of the allegations pertaining to entities other than JenaValve and therefore denies the allegations. To the extent this paragraph pertains to JenaValve, JenaValve denies these allegations. Further, to the extent the second and third sentences purport to quote a document, JenaValve respectfully refers the Court to the documents and denies any mischaracterization of their contents.

48. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

49. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations.

50. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations. Further, JenaValve incorporates by reference its responses to Paragraphs 1 through 49.

51. This paragraph asserts legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations. JenaValve specifically denies that the proposed acquisition may substantially lessen competition or tend to create a monopoly.

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The remainder of the Complaint reflects a notice and notice of contemplated relief, as well as legal conclusions and allegations to which no answer is required. To the extent an answer is required, JenaValve denies the allegations and denies that the Commission is entitled to any relief.

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### **OTHER DEFENSES**

Defendant asserts the following additional defenses to the Complaint, each of which independently and collectively demonstrates the Complaint's fundamental legal and factual deficiencies. The allegations fail to establish the essential elements of a viable claim, including the existence of a relevant product and geographic market, the presence of lawful and cognizable competition, and any reasonable probability of imminent market entry by Edwards.

The Complaint relies on speculative assertions regarding future competition and harm, unsupported by concrete facts or plausible allegations of injury to competition, innovation, or consumer welfare. It further disregards the dynamic nature of the medical device industry, including the likelihood of new entrants and the substantial procompetitive benefits and efficiencies generated by the transaction.

The Complaint also suffers from constitutional infirmities, including lack of standing and violations of separation-of-powers and due process principles. Finally, neither the initiation of this action nor the relief sought serves the public interest. Accordingly, Defendant respectfully submits that the Complaint should be dismissed in its entirety.

1. Failure to state a claim upon which relief may be granted.
  - a. Failure to allege a proper relevant product market.
  - b. Failure to allege a valid geographic market.
  - c. Failure to allege that lawful, cognizable, commercial competition exists between JenaValve and Edwards with respect to TAVR-AR devices used in clinical trials.
  - d. Failure to allege reasonable probability or timely entry by Edwards into lawful marketing and commercialization of TAVR-AR devices absent the transaction.
  - e. Failure to allege harm to competition.
  - f. Failure to allege substantial lessening of innovation competition.
  - g. Failure to allege harm to consumers or patient welfare.

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2. Failure to account for entry and competitive dynamics.
  - a. The Complaint fails to account for the potential future entry and development of TAVR-AR products in the United States as current incentive for Edwards to enhance and accelerate development and commercialization of Trilogy and J-Valve products.
3. Failure to account for efficiencies and procompetitive benefits, as the Complaint, among other things:
  - a. Fails to account for the cognizable, merger-specific benefits of Edwards commercializing Trilogy;
  - b. Fails to account for the cognizable, merger-specific benefits of Edwards further developing and manufacturing Trilogy;
  - c. Fails to account for the significant incentives and greater ability for Edwards to develop and commercialize both the Trilogy and J-Valve platforms;
  - d. Fails to account for the cognizable, merger-specific benefits of Edwards obtaining access to JenaValve intellectual property that can help develop and commercialize J-Valve and facilitate improved next-generation valve design, and
  - e. Fails to account for the cognizable, merger-specific benefits that would result from Edwards having access to a broader base of procedure outcomes in design of next-generation products.
4. Lack of Standing – Unconstitutionality of FTC Authority



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- a. FTC's exercise of rulemaking, prosecutorial, and adjudicative powers violate the separation-of-powers doctrine and Article III of the U.S. Constitution.
5. Neither the filing of this Complaint nor the relief contemplated is in the public interest, pursuant to 15 U.S.C. § 45.
6. The Administrative Proceedings violate JenaValve's Fifth Amendment due process rights.

### Notice of Contemplated Relief

JenaValve requests that the Court:

- A. Dismiss the Complaint with prejudice;
- B. Deny the Commission's requested relief;
- C. Award to JenaValve the costs incurred in defending this action, including expert's fees and reasonable attorney's fees;
- D. All further relief as the Court may deem just and proper.

Dated: August 18, 2025

Respectfully submitted,

/s/ Jonathan Klarfeld

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**Certificate of Service**

I hereby certify that, on August 18, 2025, I caused the foregoing to be electronically filed with the Secretary of the Commission using the Federal Trade Commission's e-filing system, causing the document to be served on the following registered participants.

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I also certify that I caused an unredacted copy of the foregoing document to be served via email to:

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August 18, 2025

/s/ Jonathan Klarfeld  
Jonathan Klarfeld

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**Certificate for Electronic Filing**

I hereby certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 18, 2025

/s/ Jonathan Klarfeld  
Jonathan Klarfeld